

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

US INVENTOR, INC., *et al.*,

Plaintiffs,

v.

ANDREW HIRSHFELD, in his official capacity
performing the functions and duties of the Under
Secretary of Commerce for Intellectual Property and
Director, United States Patent and Trademark Office,

Defendant.

No. 2:21-cv-00047

DEFENDANT'S MOTION TO DISMISS

MOTION TO DISMISS

For the reasons set forth in the accompanying memorandum of law, Defendant respectfully moves the Court to dismiss this action for lack of jurisdiction, *see* Fed. Rule Civ. P. 12(b)(1), and in the alternative for failure to state a claim, *see id.* 12(b)(6).

Dated: April 12, 2021

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MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT

Plaintiffs Tinnus Enterprises, LLC, 360 Heros, Inc., Ramzi Maalouf, Larry Golden, World Source Enterprises, LLC, and E-Watch, Inc. (the “Patent Owner Plaintiffs”) and Plaintiff US Inventor Inc. (collectively, “Plaintiffs”) have brought suit under the Administrative Procedure Act (“APA”) to set aside certain U.S. Patent and Trademark Office (“USPTO”) policies governing the factors that the agency considers when deciding whether to institute an inter partes review (“IPR”) proceeding and to compel the USPTO to promulgate new policies through notice-and-comment rulemaking. Am. Compl. Decl. & Inj. Relief, ECF No. 6 (“Amended Complaint”).

Plaintiffs lack standing because they cannot identify any legally cognizable concrete interest affected by the bare procedural injuries they allege. Controlling case law holds that potential parties to IPR do not have a legal right either to institution or to avoid institution of proceedings. The incidental impacts of IPR on which Plaintiffs rely in an attempt to avoid this conclusion are insufficient to establish standing.

Even if this Court had jurisdiction over Plaintiffs’ claims, they fail as a matter of law. Count I, which seeks to compel rulemaking on the factors for discretionary denial of IPR petitions, is both procedurally barred and substantively baseless. Not only have Plaintiffs failed to properly exhaust their administrative remedies with regard to this claim, but the claim erroneously attempts to apply a statute concerning the minimum standard for the grant of IPR petitions to the discretionary denial of IPR petitions. Count II, which seeks to set aside existing factors considered when deciding whether to institute an IPR proceeding, fares no better. That claim fails because the non-exhaustive, non-dispositive factors considered when exercising discretion over the institution decision are neither a final agency action subject to challenge under the APA nor a substantive rule for which notice-and-comment rulemaking is required.

The Court should therefore dismiss the Amended Complaint for lack of subject matter jurisdiction because Plaintiffs lack standing or, in the alternative, dismiss for failure to state a claim because their claims lack merit.

STATEMENT OF THE ISSUES

1. Do Plaintiffs lack standing to challenge factors considered in the discretionary decision whether to institute IPR when there is no substantive right at issue in the IPR institution decision and Plaintiffs have failed to identify any legally cognizable concrete interest in addition to the procedural violation they allege?
2. Does the USPTO's statutory obligation to enact a regulation governing the minimum threshold required for granting IPR petitions encompass an obligation to enact a regulation governing the discretionary denial of IPR petitions?
3. Is adopting non-exhaustive, non-dispositive factors concerning the exercise of the Director's discretion over the IPR institution decision a final agency action subject to judicial review when it has no certain impact and affects only an intermediate agency action that itself implicates no legal rights?
4. Do non-exhaustive, non-dispositive factors concerning the Director's discretion over the IPR institution decision constitute a substantive rule requiring notice-and-comment rulemaking when they do not establish the rights or obligations of potential parties to IPR proceedings?

BACKGROUND

I. Statutory Framework

When Congress passed the Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284 (2011), it modified the USPTO's longstanding authority to review the patentability of existing patent claims. *See Cuozzco Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2137 (2016). Currently, the most common means of reviewing patents under the AIA is termed "*inter partes* review" or "IPR." *Id.* By filing an IPR petition, "a third party [may] ask the U.S. Patent and Trademark Office to reexamine the claims in an already-issued patent and to cancel any claim that the agency finds to be unpatentable in light of prior art." *Id.* at 2136; *see also* 35 U.S.C. §§ 311, 312 (setting forth procedural and substantive requirements for a petition to institute IPR proceedings).

“The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition . . . and any response filed . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least [one] of the claims challenged in the petition.” *Id.* § 314(a); *see also id.* § 313 (patent owner may file preliminary response). However, the AIA contains “no mandate to institute review.” *Cuozzco Speed Techs.*, 136 S. Ct. at 2140; *see also SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018). Instead, “[t]he decision whether to institute inter partes review is committed to the Director’s discretion.” *Oil States Energy Servs., LLC v. Greene’s Energy Grp.*, 138 S. Ct. 1365, 1371 (2018). The Director’s determination whether to institute review is “final and nonappealable.” 35 U.S.C. § 314(d). By regulation, the Director has delegated his authority to decide IPR petitions to the Patent Trial and Appeal Board. 37 C.F.R. § 42.4(a).

Within three months of the date that the patent owner files its preliminary response to a petition, the Board must decide whether to grant institution.¹ 35 U.S.C. § 314(b)(1). If the Board finds that a petition meets the statutory criteria for review and chooses to institute proceedings, the Board conducts a trial on the validity of the challenged patent claims. *Id.* § 6(a); *see also id.* §§ 314, 318(a). IPR trial proceedings provide the patent owner with the opportunity to further respond to the petition, to file motions, to cross-examine witnesses, and, potentially, to file a sur-reply. *Id.* § 316(a)(8); 37 C.F.R. §§ 42.22, 42.223.

Generally, within one year after granting an IPR petition, the Board must issue a final written decision based on all the evidence in the record. 35 U.S.C. § 316(a)(11); *see also Cuozzco Speed Techs.*, 136 S. Ct. at 2136. Written decisions by the Board in IPR proceedings are final agency actions that establish the legal validity of the patent claims. 35 U.S.C. § 318(a). A dissatisfied party may appeal the Board’s final written decision on patentability to the Federal Circuit. *Id.* § 318(a), § 319.

¹ If no preliminary response is filed, the decision must be made within three months of the last date it could have been filed. 35 U.S.C. § 314(b)(2).

II. Regulatory Framework

Congress conferred on the USPTO Director authority to establish regulations to “govern the conduct of proceedings in the Office.” 35 U.S.C. § 2(b)(2)(A). When it enacted the AIA, Congress charged the Director with prescribing regulations related to thirteen distinct aspects of the IPR process, including “setting forth the standards for the showing of sufficient grounds to institute a[n *inter partes*] review.” *Id.* § 316(a)(2). Notably, Congress did not instruct the Director to promulgate regulations setting forth the standards for the exercise of the discretion whether to institute IPR proceedings.² *See id.*; *see also Cunozzzo Speed Techs.*, 136 S. Ct. at 2137. In 2012, following notice-and-comment rulemaking, the Director promulgated the statutorily-mandated regulation establishing the sufficiency standard. *See Changes to Implement Inter Partes Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered Business Method Patents*, 77 Fed. Reg. 48680, 48728 (Aug. 14, 2012) (codified at 37 C.F.R. § 42.108(c)).

III. Precedential Board Opinions

In addition to empowering the Director to promulgate regulations, Congress made the Director “responsible for providing policy direction and management supervision for the” USPTO. 35 U.S.C. § 3(a)(2).³ The Director can exercise this supervision in a variety of ways, such as overseeing Board leadership, publishing guidance materials (*e.g.*, the Trial Practice Guide), issuing memoranda on the handling of recurring issues before the Board, and designating Board decisions as precedential. Pursuant to this authority, the Director issued Standard Operating Procedure 2

² Although there is no requirement for the Director to do so, the Director has issued a request for comments seeking the public’s view on, among other things, the appropriate factors to consider when deciding whether to institute review in certain specified instances. *See Request for Comments on Discretion to Institute Trials Before the Patent Trial and Appeal Board*, __ Fed. Reg. __, available as of October 19, 2020, at <https://public-inspection.federalregister.gov/2020-22946.pdf>.

³ In addition, the Director has independent authority as a Board member. *See* 35 U.S.C. § 6(a).

(“SOP 2”) in 2018, addressing the Director’s ability to provide policy direction to the Board through precedential opinions.⁴

As SOP 2 explains, the Director can designate a Board opinion (or portion thereof) as precedential. SOP 2 (ECF No. 51-2). “A precedential decision is binding Board authority in subsequent matters involving similar facts or issues.” SOP 2 at 11. Regardless of the procedural path a case has taken, “[n]o decision or portion thereof may be designated as precedential or informative pursuant to [SOP 2] without the Director’s approval,” and the Director can de-designate an opinion at any time.⁵ *Id.* at 8-11. Further, SOP 2 does not “limit the Director’s authority to issue, at any time and in any manner, [other] policy directives[,] ... including policy directives concerning the implementation of statutory provisions.” *Id.* at 1-2.

Among other decisions, the USPTO Director has designated as precedential cases that identify relevant considerations for the Board’s exercise of the Director’s discretion over IPR institution pursuant to § 314(a). Here, Plaintiffs contend that the Director violated the AIA by announcing through precedential decisions non-exhaustive, non-dispositive multi-factor analyses for the Board to consider when exercising the Director’s delegated discretion under § 314(a). *See* Am. Compl. Decl. & Inj. Relief (“Amended Complaint”), ECF No. 6, ¶¶ 24, 72-73. These precedential decisions address the various factors to consider in when determining if exercising discretion to deny institution is appropriate, such as: when the Board has already denied a petition on the same patent;⁶ when a

⁴ Available at <https://www.uspto.gov/sites/default/files/documents/SOP2%20R10%20FINAL.pdf>.

⁵ Although they are not at issue in this case, “[i]nformative decisions set forth Board norms that should be followed in most cases, absent justification, although an informative decision is not binding authority on the Board.” SOP 2 at 11.

⁶ *Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19, at 15-16 (P.T.A.B. Sept. 6, 2017) (precedential in relevant part) (reciting “non-exhaustive list of factors” announced in earlier cases) (attached as Exhibit B).

petition presents prior “art or arguments [that] are ‘the same or substantially the same’ as art or arguments previously presented to the” Board;⁷ and when a parallel district court case involving the same patent is already in progress.⁸ In each instance, the relevant considerations emerged organically over the course of multiple Board decisions. *See generally Gen. Plastic Indus. Co.*, Paper 19 at 9-10 (compiling cases); *Fintiv*, Paper 11 at 5-16 (same). Building on the Board’s collective experience ensures that these analyses further “the goals of the AIA—namely to improve patent quality and make the patent system more efficient.” *Gen. Plastic Indus. Co.*, Paper 19 at 16; *see also Fintiv*, Paper 11 at 5.

STANDARD OF REVIEW

Under Rule 12(b)(1), federal courts will dismiss a case if the plaintiff lacks standing. Fed. R. Civ. P. 12(b)(1). To avoid dismissal, the plaintiff must meet his or her burden to demonstrate standing to assert the claims in the complaint. *Choice Inc. v. Greenstein*, 691 F.3d 710, 714 (5th Cir. 2012). Courts determining whether a plaintiff has carried this burden accept as true undisputed allegations in the complaint but may also look outside the complaint to resolve jurisdictional disputes. *Id.*; *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001).

“To survive a [Rule 12(b)(6)] motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct

⁷ *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, at 7 (P.T.A.B. Feb. 13, 2020) (precedential) (attached as Exhibit C) (precedential); *see also id.* at 9 n. 10 (listing “non-exclusive factors” from earlier case).

⁸ *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, at 5-6 (P.T.A.B. Mar. 20, 2020) (precedential) (compiling “non-dispositive factors” considered in earlier cases) (attached as Exhibit D); *see also NHK Spring Co. v. Intrix-Plex Techs., Inc.*, IPR2018-00752, Paper 8, 20 (P.T.A.B. Sept. 12, 2018) (precedential) (attached as Exhibit E) (“find[ing] that the advanced state of a district court proceeding is an additional factor that weighs in favor of denying [a] [p]etition”)

alleged.” *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Meeting this standard requires that the plaintiff both state a legally valid claim and make sufficient factual allegations to support the elements of that claim. *See id.*; *Lormand v. US Unwired, Inc.*, 565 F.3d 228, 257 (5th Cir. 2009).

ARGUMENT

I. Plaintiffs Lack Standing.

For a federal court to have subject matter jurisdiction to hear a case, the plaintiff must demonstrate it has standing. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). “[T]he irreducible constitutional minimum of standing contains three elements”—(1) an injury in fact (2) caused by the allegedly wrongful conduct that (3) would be redressed by the relief sought. *Id.* To have an injury in fact, the plaintiff must have “an invasion of a legally protected interest which is (a) concrete and particularized and (b) ‘actual or imminent, not conjectural or hypothetical.’” *Id.*

The gravamen of the Amended Complaint is that the USPTO was required to issue a regulation concerning the discretionary denial of IPR petitions and that the agency issued such a policy without undertaking notice-and-comment rulemaking required for substantive agency rules. Am. Compl. ¶¶ 80-87. However, the Supreme Court held in *Summers v. Earth Island Institute*, 555 U.S. 488 (2009), that being deprived of the right to comment “without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing.” *Id.* at 496; *see also Ecosystem Inv. Partners v. Crosby Dredging, LLC*, 729 F. App’x 287, 291-92 (5th Cir. 2018). Thus, for Plaintiffs to have standing, they must establish a concrete injury.

A. The Patent Owner Plaintiffs Lack a Concrete Injury.

Congress specifically denied the parties to potential IPR proceedings any rights in connection with the decision whether to institute IPR petitions, meaning that the Patent Owner Plaintiffs cannot have the requisite concrete interest to challenge the policies governing those

decisions. 35 U.S.C. § 314(d) (“The determination by the Director whether to institute an inter partes review . . . shall be final and nonappealable.”); *Thryv, Inc. v. Click-to-Call Techs., LP*, 140 S. Ct. 1367, 1373 (2020) (“[A] party generally cannot contend on appeal that the agency should have refused ‘to institute an inter partes review.’”) (quoting 35 U.S.C. § 314(d)). Initially, petitioners have no right to institution even if otherwise meeting the statutory requirements. *See Mylan Labs. Ltd. v. Janssen Pharmaceutica, N.V.*, 989 F.3d 1375, 1382 (Fed. Cir. 2021) (denying mandamus review of IPR institution denial because “no petitioner has a right to such institution” and “such a decision is committed to agency discretion by law”). As the Supreme Court explained, the AIA contains “no mandate to institute review,” and “the agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion.” *Cuozzo Speed Techs.*, 136 S. Ct. at 2140; *see also SAS Inst., Inc. v. Iancu*, 138 S. Ct. at 1351; *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S. Ct. 1365, 1371 (2018). In other words, “the Director has complete discretion to decide not to institute review.” *St. Regis Mohawk Tribe v. Mylan Pharms., Inc.*, 896 F.3d 1322, 1327 (Fed. Cir. 2018), *cert denied* 139 S. Ct. 1547 (2019); *see BioDelivery Scis. Int’l, Inc. v. Aquestive Therapeutics, Inc.*, 935 F.3d 1362, 1365 (Fed. Cir. 2019); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016).

Likewise, patent owners do not have a justiciable right created by the institution of a proceeding. It is well-settled that instituting administrative proceedings alone does not impinge on the responding party’s rights because “the expense and annoyance of litigation is part of the social burden of living under government” and “does not constitute irreparable injury.” *FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 244 (1980) (citation omitted). Thus, in *Standard Oil*, the Court rejected the respondent’s argument that the issuance of a complaint created a “right” separately reviewable and collateral to the right in the cause of action itself. *Id.* at 246; *see also Ukiab Valley Med. Ctr. v. FTC*, 911 F.2d 261, 264 (9th Cir. 1990). Because the Patent Owner Plaintiffs have no rights that

could be implicated by the institution decision, they cannot have a concrete injury that could confer standing to challenge the manner in which the USPTO makes that decision.

The Patent Owner Plaintiffs cannot overcome this legal deficiency because none of the supposed concrete harms they identify are legally cognizable. In addition, Plaintiffs offer no reason to believe that the challenged policies—which help identify circumstances in which IPR institution should be denied, Plaintiffs’ preferred outcome—actually cause them injury. Instead, Plaintiffs offer only unsupported and irrelevant speculation that a policy governing discretionary denial of IPR petitions adopted through notice-and-comment rulemaking would be more favorable to them than the existing policies. *See Lujan*, 504 U.S. at 560; *Citizens for Better Forestry v. USDA*, 341 F.3d 961, 969–70 (9th Cir. 2003) (for procedural injury to be non-speculative, it must be “reasonably probable that the challenged action will threaten [plaintiff’s] concrete interests”); *see also City of Arlington v. FCC*, 668 F.3d 229, 244 (5th Cir. 2012) (applying harmless error standard to failure to comply with APA notice-and-comment rules).

First, the Amended Complaint alleges that the Patent Owner Plaintiffs have suffered a concrete harm because notice-and-comment rulemaking would somehow have led to a policy on discretionary denial of IPR petitions that provides greater clarity than the existing policy. Am. Compl. ¶¶ 11-13, 20, 30, 40, 51, 56, 60, 64, 75. Initially, this allegation does not satisfy the pleading requirements of the Federal Rules of Civil Procedure because it is only a conclusory assertion that does not identify anything unclear about the factors for discretionary denial of IPR petitions. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009) (“[T]he pleading standard Rule 8 announces . . . demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation.”). Indeed, the precedential Board decisions addressing discretionary denial of IPR petitions clearly enumerate the various factors relevant to the institution decision. *See, e.g., Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19, at 15-16 (P.T.A.B. Sept. 6, 2017). Moreover, a lack of legal clarity

is not a legal injury. To the contrary, federal courts may only address legal questions when cognizable, substantive legal interests are at stake. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (distinguishing between valid declaratory judgment claims and impermissible advisory opinions). Thus, a lack of clarity alone cannot be an interest sufficient to confer standing.

Second, Plaintiffs assert that they have suffered a concrete harm because a policy issued through notice-and-comment rulemaking would result in the denial of IPR petitions challenging Plaintiffs' patents. Am. Compl. ¶¶ 14-21, 40, 51, 54-57, 59. However, the USPTO's institution decision does not alter the parties' rights, so it cannot constitute a legal injury. A decision whether to institute IPR proceedings does not cancel or alter any patent claims, and it does not prevent a petitioner from raising validity arguments in other forums. *See* 35 U.S.C. § 315(e)(2). Only a final written decision issued under 35 U.S.C. § 318(a) has those effects. Moreover, there is no merit to Plaintiffs' claim that IPR proceedings "effectively determine[] the fate of the . . . patent owner" because invalidation rates are "at least 2-3 times higher than in district court proceedings." Am. Compl. ¶ 26. This claim is legally irrelevant because being compelled to participate in proceedings is not an actionable harm, even when the adjudicatory process is purportedly unfair, *ultra vires*, or otherwise improperly instituted (none of which are circumstances even alleged here). *See Triangle Const. & Maint. Corp. v. Our Virgin Islands Labor Union*, 425 F.3d 938, 947 (11th Cir. 2005) (mandatory arbitration); *Esso Standard Oil Co. v. Cotto*, 389 F.3d 212, 219-220 (1st Cir. 2004) (allegedly biased state court proceeding when judicial review was ultimately available).

Additionally, Plaintiffs' claim is both untrue and misleading. Publicly available data shows that the invalidation rates are not nearly as high as Plaintiffs claim.⁹ Moreover, Plaintiffs' comparison is

⁹ PTAB Trial Statistics FY20 End of Year Outcome Roundup, IPR, PGR, CBM, https://www.uspto.gov/sites/default/files/documents/ptab_aia_fy2020_roundup.pdf, slide 13 (providing percentages of final written decisions as a percentage of all petitions). Pursuant to Federal Rule of Evidence 201, Defendant requests the Court take judicial notice of this document. *See United States v. Cecil*, 836 F.2d 1431, 1452 (4th Cir. 1988) ("courts may take judicial notice of

faulty because it fails to consider that the Board only reaches a final written decision after determining that there is a reasonable likelihood at least one challenged claim is unpatentable. 35 U.S.C. § 314(a). Plaintiffs fail to account for either the roughly one-third of petitions that are never instituted or for the one-third of petitions that are resolved before a final written decision.¹⁰ Plaintiffs looking only to the remaining one-third of petitions that are decided by a final written decision is therefore comparing apples to oranges.

Third, Plaintiffs contend that they have suffered a concrete harm because of the cost of defending their patents in IPR proceedings. Am. Compl. ¶¶ 25, 35, 39, 40, 48, 60. However, this is just a repackaging of Plaintiffs' assertions that notice-and-comment rulemaking would yield a clearer policy or one less likely to result in IPR petitions being granted. *See id.* Again, "the expense . . . of litigation is part of the social burden of living under government" and is not recognized as a change in the defending party's rights. *Standard Oil Co. of Cal.*, 449 U.S. at 244. Thus, it cannot suffice for standing. *See Lujan*, 504 U.S. at 560 (requiring a legally protected interest for standing).

B. US Inventor Lacks Organizational Standing.

It is possible for an organization or association to have standing either by virtue of its members' standing or in its own right. *NAACP v. City of Kyle, Tex.*, 626 F.3d 233, 237-38 (5th Cir. 2010). As discussed in the preceding section, however, the Amended Complaint does not demonstrate that any of US Inventor's members have standing to pursue its claims. Thus, to meet its burden on standing, US Inventor would have to demonstrate that it has independent standing by showing that it has been forced to "divert[] significant resources" to combat the USPTO's allegedly wrongful conduct and that the "conduct significantly and 'perceptibly impaired' the organization's

official governmental reports and statistics"); *United States v. 14.02 Acres of Land More or Less in Fresno Cty.*, 547 F.3d 943, 955 (9th Cir. 2008) (same).

¹⁰ PTAB Trial Statistics FY20 End of Year Outcome Roundup, IPR, PGR, CBM, https://www.uspto.gov/sites/default/files/documents/ptab_aia_fy2020_roundup.pdf, slide 15 (29% of challenged claims were found unpatentable in final written decisions in fiscal year 2020).

ability to provide its ‘activities.’” *Id.* at 238 (quoting *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982)). However, “the mere fact that an organization redirects some of its resources to litigation and legal counseling in response to actions or inactions of another party is insufficient to impart standing upon the organization.” *Id.* (quoting *La. ACORN Fair Hous. v. LeBlanc*, 211 F.3d, 298 305 (5th Cir. 2000)); *see also Nat’l Taxpayers Union v. United States*, 68 F.3d 1428, 1434 (D.C. Cir. 1995) (“[An organization] cannot convert its ordinary program costs into an injury in fact.”).

US Inventor has not alleged any appreciable diversion of resources due to the USPTO’s allegedly wrongful failure to enact policies for discretionary denial of IPR petitions through notice-and-comment rulemaking, so cannot meet its burden on standing. The only injuries US Inventor alleges on its own behalf are the supposed denial of “authoritative and clear key information” “on the topic of how discretionary considerations impact . . . institution decision” that “it wishes to use in its routine information dispensing activities.”¹¹ Am. Compl. ¶ 12. In other words, US Inventor is asserting the same purported lack of clarity that the Patent Owner Plaintiffs do. Not only is this speculative for the reasons discussed above, but any harm would be further attenuated because US Inventor lacks any direct stake in the policy. However, “an organization does not suffer an injury in fact where it ‘expend[s] resources to educate its members and others’ unless doing so subjects the organization to ‘operational costs beyond those normally expended.’” *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 920 (D.C. Cir. 2015) (alteration in original) (quoting *Nat’l Taxpayers Union, Inc. v. United States*, 68 F.3d 1428, 1434 (D.C. Cir. 1995)). US Inventor has not alleged any additional operational costs from the alleged lack of clarity in the policy governing discretionary denial of IPR petitions. *See generally* Am. Compl. ¶¶ 11-13. Indeed, it would be hard to imagine how that would be

¹¹ Plaintiffs allege that US Inventor’s members have suffered injuries of the same types as those affecting the Patent Owner Plaintiffs, Am. Compl. ¶¶ 13-14, but such purported injuries are unavailing for the same reasons that they cannot confer standing on the Patent Owner Plaintiffs. *See* § I.A, *infra*.

possible, given that (a) nothing about the process by which a policy is adopted alters the expense of educating about it and, again, (b) Plaintiffs can only speculate about what policy would be adopted through notice-and-comment rulemaking. As such, US Inventor has failed to demonstrate standing on its own behalf.

II. Plaintiffs' Claims Lack Merit.

Neither Plaintiffs' claim to compel notice-and-comment rulemaking on the factors for discretionary denial of IPR petitions nor their claim to set aside the factors adopted pursuant to precedential Board decisions states a claim upon which relief could be granted.

A. The Court Should Dismiss Count I of the Amended Complaint.

Plaintiffs claim that the USPTO has unlawfully failed to issue a regulation through notice-and-comment rulemaking establishing standards for the exercise of the Director's discretion over the IPR institution decision. *See* Am. Compl. ¶¶ 80-83. This claim fails as a threshold matter because Plaintiffs have failed to exhaust their administrative remedies. Further, the claim lacks substantive merit because relies on a clear misreading of 35 U.S.C. § 316(b), which concerns only the minimum threshold for granting IPR institution, not the Director's discretion to deny it.

1. *Plaintiffs Have Not Exhausted Their Administrative Remedies With Regard to Their Claim to Compel Rulemaking on the Factors for Discretionary Denial of IPR Proceedings.*

Plaintiffs are not entitled to judicial review of Count I because they have failed to exhaust their administrative remedies. Under the APA, a party must file a petition for rulemaking and have it denied (actually or constructively) before that party can file an action to compel the rulemaking. *See Auer v. Robbins*, 519 U.S. 452, 459 (1997); *In re Howard*, 570 F.3d 752, 757-58 (6th Cir. 2009); *Clark v. Busey*, 959 F.2d 808, 812-13 (9th Cir. 1992); *see also In re City of Fall River, Mass.*, 470 F.3d 30, 33 (1st Cir. 2006). Until that time, there has not been a final agency action subject to APA review. *See Weight Watchers Int'l, Inc. v. FTC*, 47 F.3d 990, 992 (9th Cir. 1995); *see also Gulf Restoration Network v. McCarthy*, 783 F.3d 227, 235 (5th Cir. 2015); *In re Howard*, 570 F.3d at 757. The administrative exhaustion

requirement ensures that agencies first have the opportunity to consider any legal errors and applies so long as agency consideration of the alleged error is not futile. *See Avelar-Oliva v. Barr*, 954 F.3d 757, 766 (5th Cir. 2020).

Only US Inventor has filed a petition for rulemaking; it did so in August 2020. Am. Compl. ¶ 11. Although the USPTO has not yet decided how to proceed on the proposed rules in the petition, it has, since that time, issued a request for comments seeking the public's view on the appropriate factors to consider for discretionary denials of IPR petitions. *See Request for Comments on Discretion to Institute Trials Before the Patent Trial and Appeal Board*, 85 Fed. Reg. 66,502 (Oct. 20, 2020). When the comment period closed on December 3, 2020, the USPTO had received 822 comments from trade organizations, companies, law firms, individuals, and United States Senators.¹² The diversity of views among the 822 comments demonstrates the complexity and importance of the proper considerations when exercising discretion over the IPR institution decision. Instead of waiting for the USPTO to process this information and consider next steps, the Plaintiffs filed their Amended Complaint the very next month. Given the manifest complexity and importance of these considerations, the steps taken to date, and the time needed to engage in thoughtful rulemaking, six months (as of the date of the Amended Complaint) is not an unreasonable period in which to act such that it would constitute a constructive denial of US Inventor's petition. *See Nat'l Tank Truck Carriers, Inc. v. Fed. Highway Admin.*, No. 96-1339, 1997 WL 150088, at *1 (D.C. Cir. Feb. 27, 1997) (per curiam) ("Although the 20-month delay in acting on the petition for rulemaking is disturbing, petitioner has not yet shown "unreasonable agency delay""); *United Steelworkers of Am., AFL-CIO-CLC v. Rubber Mfrs. Ass'n*, 783 F.2d 1117, 1120 (D.C. Cir. 1986) (14-month period for issuing rule not unreasonable).

¹² Public Views on Discretionary Institution of AIA Proceedings, USPTO Executive Summary, January 2021, at 1, <https://www.uspto.gov/sites/default/files/documents/USPTOExecutiveSummaryofPublicViewsonDiscretionaryInstitutiononAIAProceedingsJanuary2021.pdf>

MCI Telecomms. Cor. v. FCC, 627 F.2d 32, 340 (D.C. Cir. 1980) (up to a “year or two” not unreasonable).

As a result, none of the Moving Plaintiffs have properly exhausted their administrative remedies before filing this lawsuit, an independent reason Plaintiffs cannot be entitled to relief as to Count I.

2. *The USPTO’s Obligation to Enact a Regulation Governing the Threshold Standard for Granting an IPR Petition Does Not Encompass an Obligation to Enact a Regulation Governing the Discretionary Denial of an IPR Petition.*

The AIA obligates the USPTO Director to “prescribe regulations . . . setting forth the standards for the showing of sufficient grounds to institute a review.” 35 U.S.C. § 316(a)(2). The Director complied with his obligation related to sufficiency in 2012. *See* Changes to Implement Inter Partes Review Proceedings, 77 Fed. Reg. at 48728 (codified as amended at 37 C.F.R. § 42.108(c)).¹³ Nothing in the language of the AIA obligates the Director to also prescribe regulations establishing standards for the denial of institution pursuant to the Director’s unreviewable discretion. *See generally* 35 U.S.C. § 316(b).

The case law further emphasizes the distinction between the minimum requirements for granting an IPR petition and the Director’s discretion to deny IPR petitions that meet these requirements. In contrast to the minimum requirement to institute review—where the Director’s discretion is constrained by the requirement that he “determine[] that . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least [one] of the claims challenged in the petition,” 35 U.S.C. § 314(a)—“the Director has complete discretion to decide not to institute review,” *St. Regis Mohawk Tribe*, 896 F.3d at 1327; *see also Mylan Labs. Ltd.*, 989 F.3d at 1382 (“The Director is permitted, but never compelled, to institute an IPR.”). In other words, as the Supreme Court acknowledged, “§ 314(a) doesn’t *require* [the Director] to institute an inter partes review even after he finds the ‘reasonable likelihood’ threshold met.” *SAS Inst., Inc. v. Iancu*, 138 S. Ct. at 1351. *See*

¹³ Any claim challenging the sufficiency of that regulation would be time barred by the six-year statute of limitations under 28 U.S.C. § 2401(a). *See Hyatt v. USPTO*, 904 F.3d 1361, 1372 (Fed. Cir. 2018).

also id. at 1361 (Breyer, J., dissenting) (“Even if there is one potentially meritorious challenge[] . . . the Director still has discretion to deny a petition.”). Plaintiffs’ attempt to conflate these two distinct aspects of § 314(a) fails in light of this controlling precedent.

B. Count II of the Amended Complaint Lacks Merit Because Providing Non-Exhaustive, Non-Dispositive Factors to Consider When Exercising the Director’s Discretion Whether to Institute IPR Proceedings Is Not a Substantive Rule Requiring Notice-and-Comment Rulemaking.

Plaintiffs claim that the USPTO could adopt policies concerning the exercise of the Director’s discretion over the IPR institution decision only through notice-and-comment rulemaking and that the policies adopted by precedential Board decision should therefore be set aside. This contention fails for two reasons. Initially, this claim is non-justiciable because the Director designating as precedential Board decisions identifying some of the relevant factors for the exercise of his discretion is not final agency action subject to judicial review under the APA. Further, even if judicial review were appropriate, non-exhaustive, non-dispositive factors for the exercise of the Director’s discretion are not substantive agency rules requiring notice-and-comment rulemaking.

1. *No Rights, Obligations, or Legal Consequences Flow Directly from the Board’s Consideration of Non-Exhaustive, Non-Dispositive Factors for the Discretionary Denial of IPR Proceedings.*

The APA permits review of only final agency actions. 5 U.S.C. § 704. Agency action is final if the action (1) “mark[s] the culmination of the agency’s decisionmaking process” and (2) is “one by which rights or obligations have been determined, or from which legal consequences will flow.”

Bennett v. Spear, 520 U.S. 154, 178 (1997) (internal citations omitted). Neither of these requirements is satisfied here. Plaintiffs’ Count II is therefore non-justiciable and should be dismissed.

Absent a statute to the contrary, the issuance of an internal agency policy is not ordinarily a final action that can be directly challenged under the APA. *See* 5 U.S.C. § 704; *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 891 (1990) (discussing regulations); *Nat’l Min. Ass’n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014) (internal agency guidance not final agency action). When an agency decision “is

a step toward, and will merge in, the [agency]’s decision on the merits . . . review of this preliminary step should abide review of the final order.” *Standard Oil Co. of Cal.*, 449 U.S. at 246; *see also Energy Transfer Partners, LP. v. FERC*, 567 F.3d 134, 144 (5th Cir. 2009) (order instituting administrative adjudication not final agency action). Even when an agency applies an allegedly unlawful policy in its adjudications, only the resulting order is a final agency action ripe for APA review. *See RCM Techs., Inc. v. DHS*, 614 F. Supp. 2d 39, 45 (D.D.C. 2009); *Arden Wood, Inc. v. U.S. Customs & Immig. Servs.*, 480 F. Supp. 2d 141, 149-50 (D.D.C. 2007); *see also Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 891 (1990) (allegedly unlawful agency policy not generally reviewable until “some concrete action appl[ies] the” policy). Here, Congress’s decision to foreclose review of the denial of an IPR petition under § 314(d) does not alter these well-established principles of administrative law.

Only in rare cases will the issuance of a policy “itself affect parties concretely enough to satisfy [the finality] requirement.” *Reno v. Catholic Social Servs., Inc.*, 509 U.S. 43, 57–61 (1993); *see also Standard Oil Co.*, 449 U.S. at 241-42. Issuance of a policy is final only when the policy directly causes “a certain change in the legal obligations of a party” or immediately forces regulated entities to alter their day-to-day affairs. *Ctr. for Auto Safety v. Nat’l Highway Traffic Safety Admin.*, 452 F.3d 798, 811 (D.C. Cir. 2006) (citation omitted); *see also Catholic Social Servs., Inc.*, 509 US at 57-58. Adopting non-dispositive factors to take into account when exercising discretion over the institution decision lacks the requisite legal effect for two reasons.

Initially, the factors are non-dispositive and non-exhaustive, so they cannot effect a certain legal change. *See Fintiv*, Paper 11 at 6 (requiring consideration of “other circumstances that impact the Board’s exercise of discretion, including the merits”); *Advanced Bionics*, Paper 6 at 9 n. 10 (listing “non-exclusive factors”); *Gen. Plastic Indus.*, Paper 19 at 16 (“non-exhaustive list of factors”). “When intermediate agency action does not bind the final decisionmaker, no final agency action has occurred.” *See Planned Parenthood of Wisc., Inc. v. Azar*, 316 F. Supp. 3d 291, 302 (D.D.C. 2018), *vacated*

as moot, 942 F.3d 512 (D.C. Cir. 2019). Although the Board is bound to consider factors identified in precedential Board decisions, the Board can nonetheless decide that those factors are outweighed by other considerations. “Although practically consequential, the [precedential decisions] describe[] how [the] agency decision *will be* made, and [their adoption] is not a final agency action itself.” *Id.* at 300.

Moreover, no substantive rights are determined by the grant or denial of institution, so the institution decision itself cannot be a final agency action under the APA. *See Fairbanks N. Star Borough v. U.S. Army Corps of Eng’rs*, 543 F.3d 586, 594 (9th Cir. 2008); *see also Nat’l Ass’n of Home Builders v. Norton*, 415 F.3d 8, 16 (D.C. Cir. 2005). As the Federal Circuit recently reiterated, “no petitioner has a right to such institution” and “such a decision is committed to agency discretion by law.” *Mylan Labs. Ltd.*, 989 F.3d at 1382; *see also Cuozzo Speed Techs.*, 136 S. Ct. at 2140 (“decision to initiate inter partes review is . . . not ‘final’” for purpose of APA review). The denial of an IPR petition leaves intact both the patent claims and the petitioner’s right to challenge those claims in federal court. *See* 35 U.S.C. §§ 315(e), 318(b). Likewise, the grant of an IPR petition preserves those rights until the Board issues a final written decision after a full hearing. *Id.* § 318(a). The institution decision merely determines “that adjudicatory proceedings will commence,” so it cannot be a final agency action. *Standard Oil Co. of Cal.*, 449 U.S. at 241-42 (final decision to issue complaint initiating proceedings not final agency action); *City of Oakland v. Lynch*, 798 F.3d 1159, 1166-67 (9th Cir. 2015) (same for forfeiture complaint). Because it is not a final agency action, the claim is not appropriate for judicial review under the APA.

2. *Factors for Discretionary Denial of IPR Institution Are General Statements of Policy, Not Substantive Rules.*

Even if Count II were justiciable, it would fail because the non-exhaustive, non-dispositive, multi-factor analyses that Plaintiffs challenge are not substantive rules requiring notice-and-comment rulemaking. *See See Lincoln v. Vigil*, 508 U.S. 182, 196 (1993) (“notice-and-comment requirements

apply . . . only to so-called ‘legislative’ or ‘substantive’ rules”). “Substantive or legislative rules affect individual rights and obligations and are binding on the courts. Non-legislative rules, on the other hand, ‘genuinely leave the agency and its decisionmakers free to exercise discretion.’” *Tex. San. & Cmty. Bankers Ass’n v. Fed. Hous. Fin. Bd.*, 201 F.3d 551, 556 (5th Cir. 2000) (internal citations omitted); *see also Paralyzed Veterans of Am. v. West*, 138 F.3d 1434, 1436 (Fed. Cir. 1998). Of relevance here, “‘general statements of policy,’ which [are] . . . ‘statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power,’” are not substantive rules. *Lincoln*, 508 U.S. at 197 (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 n. 31 (1979)). “As long as the agency remains free to consider the individual facts in the various cases that arise, then the agency action in question has not established a binding norm” and will not amount to a substantive rule. *Pros. & Patients for Customized Care v. Shalala*, 56 F.3d 592, 594–96 (5th Cir. 1995) (citation omitted).

The precedential Board decisions laying out the factors relevant to the exercise of discretion under § 314(a) all require individualized consideration. *See Fintiv*, Paper 11 at 5-6 (listing “non-dispositive factors,” including all “other circumstances that impact the Board’s exercise of discretion, such as the merits”), *Advanced Bionics*, Paper 6 at 9 n. 10 (“non-exclusive factors”); *General Plastic Indus. Co.*, Paper 19 at 16 (“non-exhaustive list of factors”). They identify certain considerations that the Board takes into account when exercising the Director’s discretion. Policies that are “not outcome determinative” (*i.e.*, non-dispositive rules) cannot have force of law and therefore cannot be substantive rules. *Planned Parenthood of Wis., Inc.*, 316 F. Supp. 3d at 307-08 (criteria for formulating grant recommendations not substantive rule); *see Clarian Health W. LLC v. Hargan*, 878 F.3d 346, 358 (D.C. Cir. 2017) (criteria governing discretionary decision not a legislative rule).

Indeed, the instant case is directly analogous to the Fifth Circuit’s holding in *Professionals and Patients for Customized Care*, 56 F.3d 592. There, a federal agency announced a non-exhaustive list of

nine factors for its employees to follow when deciding whether to institute enforcement proceedings. *Id.* at 593-94. The factors were also non-dispositive, in that “even if the factors [were] present] the [agency] retain[ed] discretion whether to bring an enforcement action.” *Id.* at 597-98. In light of these characteristics, the Fifth Circuit concluded that it was “clear that the nine factors . . . are not the type of criteria that courts have traditionally characterized as ‘binding norms’” and therefore did not constitute a substantive rule for purposes of the APA. *Id.* at 599. Here, the same is true of the non-exhaustive, non-dispositive factors that the USPTO has identified as relevant to the Board’s exercise of discretion with regard to the decision whether to institute IPR proceedings. Although the Board must consider the identified factors, that does not dictate the outcome of the institution decision. The Board’s exercise of discretion based on the particular facts of any given case belies Plaintiffs’ claim that the challenged precedential Board decisions constitute substantive rules.

CONCLUSION

For the reasons set forth herein, the Court should dismiss this action for lack of jurisdiction, or in the alternative, for failure to state a claim.

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